

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

In re Bair Hugger Forced Air Warming
Products Liability Litigation

MDL No. 2666 (JNE/FLN)

This Document Relates to
ALL ACTIONS

**DEFENDANTS' MEMORANDUM IN RESPONSE TO PLAINTIFFS' MOTION
TO EXCLUDE THE OPINIONS AND TESTIMONY OF
JOHN ABRAHAM, PH.D.**

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INTRODUCTION

Plaintiffs' motion to exclude the opinions and testimony of defense expert Dr. John Abraham should be denied. Dr. Abraham calculated airflow using computational fluid dynamics (CFD), and validated his results with an airflow visualization study in an actual operating room.¹ Dr. Abraham's CFD and airflow visualization study, which show the Bair Hugger system does not disrupt operating room airflow or lift pathogens from the floor and deposit them on the surgical site, were published in *Numerical Heat Transfer*—the leading journal specializing in heat transfer calculations.² Without any scientific or other support, Plaintiffs incorrectly theorize that Dr. Abraham's CFD modeling of airflow (*i.e.*, air molecules, displayed as streamlines in his report)³ is not relevant, his CFD cannot be replicated, and his CFD and airflow visualization study are not reliable. Plaintiffs' arguments are premised on theories *they* devised—none of which are grounded in science, facts, or the law—and mischaracterize the testimony, issues, and evidence in the litigation.

Dr. Abraham is a highly qualified expert in heat transfer and fluid flow, with extensive experience in airflow experiments and CFD calculations. DX1, Expert Report

¹ As explained by NASA, CFD validation is “the process of determining the degree to which a model is an accurate representation of the real world from the perspective of the intended uses of the model.” (<https://www.grc.nasa.gov/www/wind/valid/tutorial/valassess.html>).

² <http://www.scimagojr.com/journalrank.php?category=2612>.

³ A streamline is the path air is following. In other words, streamlines are airflow lines.

of John Abraham, Ph.D. (“Abraham Rpt.”) at 1.⁴ His specialties include air flow, laminar flow, ventilation, turbulent flow, particle movement in turbulent flow, heat transfer involving the human body, heating blankets used during surgeries, and buoyancy (flow caused by heating). *Id.* at 1, Ex. A; DX2, Deposition of John Abraham, Ph.D. (“Abraham Dep.”) at 124:6-19. Dr. Abraham has worked on the design and analysis of patient thermal warming blankets, published approximately 160 journal papers, given approximately 120 presentations, written and edited multiple books and book chapters, and authored several patents. DX1, Abraham Rpt. at 1.

In the current litigation, Dr. Abraham was asked to examine whether air from the Bair Hugger patient warming system is capable of disrupting clean operating room airflow, or lifting pathogens from the floor or underneath the surgical table and depositing them onto the surgical site.⁵ To answer these questions, he created a CFD model (a computerized rendition) of an operating room at Fairview Southdale Hospital in Edina, Minnesota. His CFD model, which used measurements taken in the operating room, included the room air space, inlets and outlets where air enters and leaves the room, a patient, surgical drape, operating table, and various obstructions such as surgical lights. DX1, Abraham Rpt. at 3. Using Large-Eddy Simulation (LES), the preferred methodology to calculate airflows that

⁴ All citations to “DX” in this Memorandum are exhibits to the concurrently filed Declaration of Peter J. Goss.

⁵ These claims, raised by Dr. Augustine in marketing materials and online videos as early as 2010, have been adopted and parroted by Plaintiffs’ experts, including their CFD expert Dr. Said Elghobashi. See <https://www.youtube.com/watch?v=hdtiBgUFzdc>; <https://www.youtube.com/watch?v=BKFl2rINa9g&t=443s>; DX3, ECF No. 810-1 at 77, Elghobashi Rpt. at Ex. 2, p. 2.

are unsteady and contain buoyancy, Dr. Abraham calculated the airflow and temperature in the operating room and from the Bair Hugger system.⁶ *Id.* at 5. To test and validate the calculations in his computerized CFD model, Dr. Abraham then performed a real-life airflow visualization study in the operating room at Fairview Southdale Hospital.⁷ *Id.* at 5–6. During the airflow visualization study, which included a surgical team, patient, operating table and various obstructions, airflow patterns were visualized through the injection of visible water vapor (a dense cloud) into the room when the Bair Hugger was on and when it was off. *Id.* at 10.

Both the CFD and the airflow visualization study confirmed that air from the Bair Hugger system (1) did not disrupt operating room airflow or prevent clean air from washing over the patient and surgical site, and (2) did not lift pathogens from the floor and deposit them onto the surgical site. *Id.* at 12. Moreover, air from the Bair Hugger system quickly mixed with the operating room airflow, and the patterns of airflow were the same when the Bair Hugger system was on and when it was off. *Id.* at 10. Dr. Abraham therefore concluded that forced air patient warming does not meaningfully impact airflow currents

⁶ Notably, Plaintiffs' CFD expert Dr. Elghobashi also recognized that the LES method is the appropriate and “essential” methodology to use. DX3, ECF No. 810-1 at 22, Elghobashi Rpt., Ex. 1 at 18. Furthermore, Dr. Elghobashi admitted during his deposition that he did not perform the CFD upon which he relies in his report; rather it was performed by a Professor Apte using a proprietary program. DX4, Deposition of Dr. Said Elghobashi (“Elghobashi Dep.”) at 55:4–56:2, 126:1-6.

⁷ Although he has written numerous papers stating that validation is necessary and teaches that to his students, Dr. Elghobashi did not validate the CFD upon which he relies in the litigation. DX4, Elghobashi Dep. at 128:8–131:16, 133:12–135:13, 137:5–139:14; DX5, Elghobashi Dep. Exs. 15–17.

in operating rooms, nor does it increase the risk that airborne bacteria and bacteria-carrying particles will reach the surgical site during a procedure. *Id.* at 2. Dr. Abraham also reviewed relevant scientific literature, and concluded that it is consistent with his CFD calculations and airflow visualization study. *Id.* at 2, 12–15. Dr. Abraham’s experiments, opinions, and testimony are relevant and reliable, and therefore satisfy the requirements of *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), Minn. R. Evid. 702, and *Goeb v. Tharaldson*, 615 N.W.2d 800 (Minn. 2000).

ARGUMENT

I. DR. ABRAHAM IS QUALIFIED TO RENDER HIS OPINIONS, AND HIS CFD MODELING AND AIRFLOW VISUALIZATION STUDY ARE RELEVANT AND RELIABLE.

A. Dr. Abraham is Qualified to Testify that the Bair Hugger System Does Not Disrupt Operating Room Airflow and is Not Capable of Causing Particles or Bacteria to Reach the Surgical Site.

Dr. Abraham, a professor of thermal sciences who has worked at the University of St. Thomas in St. Paul, Minnesota for over 15 years, teaches, researches, publishes, and consults in the areas of heat transfer, airflow, and other fluid flow. DX1, Abraham Rpt. at 1. As discussed above, Dr. Abraham specializes in numerous subject matters, including airflow, laminar flow, ventilation, turbulent flow, particle movement in turbulent flow, heat transfer involving the human body, heating blankets used during surgeries, and buoyancy (flow caused by heating). *Id.* at 1, Ex. A; DX2, Abraham Dep. at 124:6-19. Dr. Abraham possesses the necessary expertise, in the form of “knowledge, skill, experience, training, or education,” to render his opinions. *See Fed. R. Evid. 702; Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc.*, 254 F.3d 706, 715 (8th Cir. 2001).

Based on his own CFD and airflow visualization study, Dr. Abraham opined that “forced-air patient warming does not meaningfully impact air flow currents in operating rooms and does not increase the risk that airborne bacteria and bacteria-carrying particles will reach the surgical site during a procedure.” DX1, Abraham Rpt. at 2. He further concluded, “Claims that the Bair Hugger exhaust air somehow travels down to the operating room floor, picks up bacteria, loft them above the surgical table, and finally deposits them in the surgical zone are contradicted by both numerical simulation and by experimentation and by basic laws of physics.” *Id.* at 12.

Notably, Plaintiffs do not challenge Dr. Abraham’s expertise in CFD or airflow visualization techniques, or argue that he is unqualified to render an opinion based on these disciplines. Instead, Plaintiffs argue that Dr. Abraham’s CFD modeling of air molecules is not relevant to the facts of the case (see Section C below). Plaintiffs further challenge Dr. Abraham’s ability to testify regarding particle flow, by cherry-picking and mischaracterizing his testimony. For example, Plaintiffs falsely claim that Dr. Abraham “admitted in his deposition that he is not an expert in particle flow.” Pl. Mem. at 2 (citing DX2, Abraham Dep. at 246:3-8). What Dr. Abraham actually said, however, is that he is not an expert in particles *in high or low speed flows*. *Id.* (High speed flows include flows through engines and rockets, and low speed flows are extremely slow and sometimes categorized as “creeping” flows—neither are the type of flow in operating rooms and therefore are not relevant to the case). As it relates to this case, Dr. Abraham explicitly stated that he is an expert in particle movement in a turbulent flow:

Q. Do you consider yourself an expert in particle flow?

A. Yes.

Q. Do you consider yourself an expert in particle movement in a turbulent flow?

A. Well, I've done multiple studies on movement of objects and particles in a turbulent flow, so -- and multiple peer-reviewed studies. Does that make me an expert? I don't know. I'd have to think about that.

Q. Well sitting here today, I mean, I understand you want to think about it, but I need a[n] answer.

A. I consider myself an expert.

DX2, Abraham Dep. at 124:6-19.

B. Dr. Abraham is Qualified to Testify that the Bair Hugger System Does Not Increase the Risk of Surgical Site Infections.

Based upon his own testing, Dr. Abraham concluded:

My opinion is that there is no compelling evidence that the use of forced-air warming systems such as the Bair Hugger meaningfully disrupt operating room airflow and therefore do not increase the risk of surgical site infection by that purported mechanism. Claims that the Bair Hugger exhaust air somehow travels down to the operating room floor, picks up bacteria, loft them above the surgical table, and finally deposits them in the surgical zone are contradicted by both numerical simulation and by experimentation and by basic laws of physics.

DX1, Abraham Rpt. at 12.

Plaintiffs nevertheless claim that Dr. Abraham should not be allowed to testify about the risk of surgical site infections because he is not an infectious diseases doctor, medical doctor, epidemiologist, or surgeon, and therefore does not have training in biology. Pl. Mem. at 21. But he does not have to be. His own CFD and airflow visualization study,

grounded in reliable methodologies, confirm what numerous healthcare organizations have already concluded: that the Bair Hugger is not capable of causing surgical site infections.⁸

C. Dr. Abraham's CFD and Airflow Visualization Study are Relevant.

Plaintiffs' argument that Dr. Abraham's modeling of air streamlines instead of particles makes his CFD irrelevant is belied by numerous peer-reviewed studies that used CFD modeling of air streamlines to examine particles in operating rooms.⁹ Indeed, Dr. Abraham's modeling of air molecules is actually favorable to Plaintiffs' theories because air molecules are *more* likely to reach the surgical site than particles.¹⁰ Simply put, because

⁸ Dr. Abraham's opinion is supported by numerous independent organizations who have recognized that patient warming, including forced-air warming, is important for patient care, and there is no evidence of a causal link between forced-air warming and surgical site infections. *See* ECF No. 762, Defendants' Mem. in Support of Mot. for Summary Judgment at 17–20. On August 30, 2017, the United States Food & Drug Administration (FDA) issued a letter to healthcare providers recommending “the use of thermoregulating devices (including forced air thermal regulating systems) for surgical procedures when clinically warranted,” stating, “After a thorough review of available data, the FDA has been unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection.” ECF No. 751-1 at 2, August 30, 2017 Letter from United States Food & Drug Administration titled “Forced Air Thermal Regulating Systems: Healthcare Provider Letter – Information About Use.”

⁹ *See, e.g.*, Tung et al., “Numerical study on the dispersion of airborne contaminants from an isolation room in the case of door opening,” 29 *Applied Thermal Engineering* 1544, 1547 (2009); Brohus et al., “Influence of disturbances on bacteria level in an operating room,” 16 *Indoor Air* 356 (2008); Saarinen et al., “Large Eddy Simulation of Air Escape through a Hospital Isolation Room Single Hinged Doorway—Validation by Using Tracer Gases and Simulated Smoke Videos,” 10(7) *PLoS ONE* e0130667 (2015); Srebric et al., “CFD boundary conditions for contaminant dispersion, heat transfer and airflow simulations around human occupants in indoor environments,” 43 *Building & Env't* 294 (2008).

¹⁰ Plaintiffs also misconstrue the testimony of Defendants' experts Dr. Settles and Dr. Kuehn. *See* Pl. Mem. at 13. Neither are critical of Dr. Abraham's methods. Dr. Settles simply explained that because Schlieren techniques have no effect on airflow patterns

particles have mass and inertia that is higher than their surrounding air, they are more likely to settle out of the air, and less likely to reach the surgical site than air molecules (which have no mass or inertia and are therefore more likely to reach the surgical site). During his deposition, Dr. Abraham explained that his modeling of air represents a worst-case scenario:

Q. So you assumed that airflow was the worst-case scenario as compared to particle flow?

A. Yes.

Q. And your basis behind that assumption?

A. Simple. Particles have a mass that is higher than their surrounding air, so particles like to settle out of the air. And in fact Said Elghobashi found his equivalent diameter by using the settling diameter. Particles like to fall out of the flow. Furthermore, particles have inertia. Multiple experts have already testified to this fact. Particles have inertia, and they find it hard to follow curved streamlines, and that tends to bring particles out of the flow.

So for those two reasons I decided to use the worst-case scenario, which is air. I tracked air particles which have no gravity term and no inertia term. So in that respect it's a worst-case calculation.

being studied, they are *more* reliable for revealing true thermal airflow patterns than particle-tracer methods which do impact airflow patterns. Dr. Settles reached the same conclusions as Dr. Abraham: that forced air warming does not disrupt laminar flow because laminar flow easily sweeps the forced-air convection currents away, and forced air warming cannot and does not mobilize floor air to the surgical site. *See* DX6, ECF No. 834-1, Settles Rpt. at 3, 21. When asked whether one must use Lagrange (a method used by Dr. Elghobashi) to track particles in a turbulent flow, Dr. Kuehn did not agree that it was required. He actually testified several times, including in the testimony cited by Plaintiffs, that streamlines can be used to measure particles, but it depends on the particle size, the speed at which the airflow changes direction, and the velocity of the particles. DX7, Kuehn Dep. at 195:16–196:24 and 204:4–23.

DX2, Abraham Dep. at 227:14–230:8.

Throughout this litigation, Plaintiffs have parroted theories devised by Dr. Augustine and researchers he funded; namely, that the Bair Hugger system disrupts operating room airflow, and its warm air stirs pathogens from underneath the surgical table and deposits them on the surgical site.¹¹ *See* Pl. Master Long Form Compl. at 2, 9–10. Plaintiffs’ experts, including their CFD expert Dr. Said Elghobashi, also adopt these arguments. DX3, ECF No. 810-1 at 77, Elghobashi Rpt. at Ex. 2, p. 2. Notably, no study (including those that Plaintiffs rely on) is able to demonstrate a causal link between the Bair Hugger system and any infection. Dr. Abraham’s experiments, testimony and opinions thus directly contradict arguments made by Plaintiffs and their experts. To show that expert testimony is relevant, a proponent must show that the reasoning or methodology in question is applied properly to the facts in issue and that the testimony will assist the trier of fact to understand or determine a fact in issue. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591–93 (1993). As explained above, Dr. Abraham’s CFD and airflow visualization study are properly applied to the facts in this case and will assist the trier of fact in determining whether the Bair Hugger system is capable of causing surgical site infections. Dr. Abraham has relevant, reliable, and helpful testimony to provide regarding his airflow studies. Plaintiffs’ motion should be denied.¹²

¹¹ *See* <http://heat-rises.blogspot.com/>.

¹² Plaintiffs’ arguments on pages 21–22 (sections b, c and 2) focus on areas that Defendants are not offering Dr. Abraham as an expert, but nonetheless mischaracterize the facts. Defendants are not offering Dr. Abraham as an expert on warming technologies, but he appropriately states, citing nine studies, that “[t]he use of warming technologies to maintain patient temperatures is an important part of surgical patient care.” DX1, Abraham Rpt. at

II. DR. ABRAHAM'S OPINIONS AND TESTIMONY ARE GROUNDED IN RELIABLE METHODOLOGY.

As explained in his report, the technique of computational fluid dynamics (“CFD”) is a mature science that has been developed over many decades. CFD is employed in numerous industries and has been used to model diverse fluid flows, including airflow in operating rooms, blood flow in the heart and arteries, and airflow over aircraft and space vehicles. It is based on fundamental physical principles (conservation of mass, conservation of momentum, and conservation of energy) and involves physics equations which are solved at a multitude of locations (called “grid cells”) distributed throughout the fluid space (in this case, air). DX1, Abraham Rpt. at 2. Numerous courts have recognized the benefits of CFD. *See* Pl. Mem. at 9–11.¹³

12. Dr. Abraham never states that Dr. Elghobashi’s CFD was performed at the direction of a business competitor, he states a known fact: “*The contrary view* is unsupported by the facts and relies upon poorly performed and described research completed at the direction of a business competitor.” *Id.* at 2 (emphasis added). Plaintiffs and their experts, including Dr. Said Elghobashi, adopt Dr. Augustine’s theories, shown on his “heat-rises” blog, that heat from the Bair Hugger system causes particles to enter the surgical field. *See supra* n. 11. It is thus appropriate for Dr. Abraham to rebut these claims by analyzing the “heat-rises” blog videos. *See Aviva Sports, Inc. v. Fingerhut Direct Marketing, Inc.*, 829 F. Supp. 2d 802, 835 (2011) (rebuttal expert’s role is “to critique plaintiffs’ expert’s methodologies and point out potential flaws in the plaintiff’s experts’ reports.”).

¹³ Plaintiffs launch a series of false attacks on Dr. Abraham’s CFD, none of which is pertinent to his experiments’ relevance and reliability. For example, Plaintiffs incorrectly claim that Dr. Elghobashi used actual solids and materials in his model when Dr. Abraham did not—but Dr. Elghobashi did not use solids and materials. *See* DX3, ECF No. 810-1, Elghobashi Rpt., Ex. 1 at 31–32. Plaintiffs claim that Dr. Abraham had insulated surfaces to represent solid objects—but so did Dr. Elghobashi. *Id.* Plaintiffs claim that Dr. Elghobashi created his own geometry—he did not. DX4, Elghobashi Dep. at 193:13–19. Plaintiffs state that Dr. Abraham did not include people in his model. This was intentional, as he wanted to model whether the Bair Hugger can change the airflow in a room with moving people. Plaintiffs argue that Dr. Abraham did not include the Bair

When assessing an expert's testimony and opinions for relevance and reliability, the court should consider, among other factors, (1) whether the theory or technique "can be (and has been) tested;" (2) "whether the theory or technique has been subjected to peer review and publication;" (3) "the known or potential rate of error;" and (4) whether the theory has been generally accepted. *Daubert*, 509 U.S. at 593, 594; *Peitzmeier v. Hennessy Indus., Inc.*, 97 F.3d 293, 296–97 (8th Cir. 1996). As explained further below, Dr. Abraham produced his TRN file, which allows Plaintiffs to test and replicate his CFD. In addition, he tested and validated his CFD through an airflow visualization study in an actual operating room, achieving the same results. Dr. Abraham's CFD and airflow visualization study results were also published.¹⁴

A. Dr. Abraham Provided the Methodology, Equations and Files Necessary for Plaintiffs to Test and Replicate His CFD Results.

Dr. Abraham provided detailed information concerning the methodologies used for his CFD and airflow visualization studies, and he provided all of the files and information required for Plaintiffs to test his CFD and replicate his results.¹⁵ Plaintiffs' suggestion that

Hugger blower in his model, but he included the air blown through the Bair Hugger into the blanket and then into the room—modeling the worst-case scenario.

¹⁴ DX8, Abraham et al., "Comprehensive review and study of the buoyant airflow within positive-pressure hospital operating rooms," 72(1) *Numerical Heat Transfer, Part A: Applications* 1 (2017). In addition, Dr. Abraham's calculations were confirmed by defense experts Dr. Settles and Dr. Kuehn's independent experiments.

¹⁵ Notably, Plaintiffs had Dr. Abraham's TRN file (which allows them to replicate his results) for approximately eight months before deposing Dr. Abraham. During that time neither Plaintiffs nor Dr. Elghobashi ever stated that the files prevented replication of Dr. Abraham's results.

Dr. Elghobashi (a “world class” CFD expert) cannot replicate Dr. Abraham’s CFD with Abraham’s master file lacks any merit. In addition, Plaintiffs’ argument that Dr. Abraham did not disclose enough information is dubious. Surely a “world class” expert like Dr. Elghobashi could recite the relevant equations in his sleep. Moreover, Plaintiffs completely refused to produce Dr. Elghobashi’s CFD, claiming it was proprietary. Plaintiffs’ claims that Dr. Abraham’s results cannot be tested or reproduced are disingenuous, to say the least.

For example, Plaintiffs claim that Dr. Abraham’s report does not contain a description of his methodology sufficient to allow others to reproduce his results. Pl. Mem. at 3–4. Once again, Plaintiffs misrepresent the facts. Dr. Abraham’s report contains a detailed methodology, which includes the six-step process used for deriving his conclusions, and confirms that (like Plaintiffs’ own expert, Dr. Elghobashi) Dr. Abraham used the LES method. DX1, Abraham Rpt. at 2–6.

Plaintiffs are also wrong when they argue that Dr. Abraham failed to indicate which engineering equations he used or what conditions he set. Pl. Mem. at 2.¹⁶ Dr. Abraham disclosed in his report that he used the LES method and Boussinesq equations, and provided the TRN file for his CFD which contained the equations. DX2, Abraham Dep. at

¹⁶ Plaintiffs falsely claim that Dr. Elghobashi disclosed more information and detail than Dr. Abraham. Pl. Mem. at 4. For example, they state that Dr. Elghobashi produced all of the mathematical equations used in his CFD simulation—however, he did not supply equations related to the discretization of the model (solving differential equations on a grid), equations relating to the coefficients used in the calculation of eddy viscosity and thermal diffusivity, and did not write his equation for time-step progression.

212:4-8, 366:7-17; DX1, Abraham Rpt. at 5. In addition, Dr. Abraham testified that the equations are publicly available in the ANSYS theory manual:

Q. Sitting here today I cannot determine, or anyone on my team, or my consultants, whether or not the equations that you used are the appropriate equations for the model because you did not inform me what the equations are; correct?

A. You know that I used the LES method. The equations -- If you need to see the equations written down they would be contained within the ANSYS theory manual. So yes, sitting here today you could.

DX2, Abraham Dep. at 221:25–222:11.

Regarding the “initial conditions” and “time step”¹⁷, Plaintiffs either misunderstood Dr. Abraham’s testimony, misunderstand the science, or both. Dr. Abraham clearly explained that Plaintiffs do not need the initial conditions or the time step to reproduce his results:

Q. And you have not provided the initial conditions to the plaintiff in this case; correct?

A. That is correct.

Now you can get the same results by having different initial conditions.

¹⁷ The results of a CFD model do not depend on the initial conditions, and Plaintiffs can reproduce Dr. Abraham’s calculations by using his final results (the TRN file) as their initial conditions. DX2, Abraham Dep. at 54:21-23. Time steps are an internal clock used by the CFD software and have nothing to do with the time corresponding to the flow along its trajectory. For instance, the software could show the air molecules emerging from the blanket and track them for 30 to 60 seconds even though the internal clock of the computer has not advanced 30 to 60 seconds. Provided one uses a sufficiently small time step, a solution to the airflow can be obtained. One can demonstrate the accuracy of the solution by comparison with experiments.

Q. But the methodology requires initial conditions; correct?

A. The methodology requires initial conditions but it doesn't require the same ones.

* * * *

Q. Okay. Without the time step can I reproduce your results?

A. Yes.

Q. But you just told me it was very important to reproduce the results.

A. Correct.

Q. So without it and it's an important piece of information to reproduce results, how would I reproduce your results without a time step?

A. And actually let me clarify my earlier answer.

Provided that your time step is sufficiently small and that it allows you to reach quasi-steady results, you would be able to reproduce these results.

DX2, Abraham Dep. at 254:1-11, 68:13–69:1; *see also id.* at 296:14-18.

Plaintiffs incorrectly claim that to reproduce a CFD model, one must indicate the equations used, the initial conditions, the time step used, the mesh, and then determine whether the quasi steady state has been reached; *i.e.*, whether there is a solution to the equations. Pl. Mem. at 15. They then claim that Dr. Abraham admits that without the initial conditions, the time step, and more than one data file, his CFD model cannot be reproduced. Again, Plaintiffs misrepresent and mischaracterize Dr. Abraham's testimony. When Plaintiffs asked Dr. Abraham if it would be possible to replicate his results without

the initial conditions and time step data, he clearly explained that Plaintiffs do not need the initial conditions or time step data, and could use the TRN file to replicate his work:

Q. Okay. Otherwise without those data -- that data, it would be impossible for me to replicate the results you found in your 264 TRN file; correct?

A. I disagree.

Q. How would I replicate and get the exact same numbers -- I'm not talking about your judgement -- I'm talking about the exact same calculated numbers in the 264 TRN file, if I don't have the initial conditions?

A. You're using the word "replicate" in a way that's not the way it's used in our field. To replicate, and I mentioned this before, "replicate" doesn't mean to do the exact same thing with the exact same methodology, but it's to come up with the same results and conclusions. You are able -- Anyone is able to replicate my work simply from that TRN file. Now that doesn't mean that at the 264th time step they will have the exact same numbers, but it means that if they do the problem right, they will come to the exact same conclusions.

DX2, Abraham Dep. at 71:18–72:11; *see also id.* at 196:14–18.

Dr. Abraham provided the file which contains the geometry, mesh, boundary conditions and the actual results, as he confirmed in his deposition:

Q. Can I reproduce your model through the TRN?

A. Yes.

Q. How would I do that?

A. The TRN contains all of the information, including the geometry, the mesh, the boundary conditions, the time stepping information. The TRN actually contains everything.

DX2, Abraham Dep. at 54:21–55:3. From the file Dr. Abraham provided, Plaintiffs can reproduce his results. In fact, Plaintiffs displayed and manipulated his CFD on a projector screen during his deposition. Dr. Abraham kept and produced the files necessary for Plaintiffs to replicate his results; Plaintiffs’ complaints to the contrary are baseless.

B. Dr. Abraham’s Airflow Visualization Study is Based on a Reliable Methodology.

To validate his calculations, Dr. Abraham performed real-life experiments in the operating room at Fairview Southdale Hospital in Edina, Minnesota. DX1, Abraham Rpt. at 10. As explained in his report, his goal was to demonstrate airflow patterns in an actual operating theater with a surgical team and a patient. *Id.* During the experiments, airflow patterns were visualized by injecting visible water vapor (a dense cloud) into the room. *Id.* The water vapor was injected in two scenarios: first with the Bair Hugger on; second with the Bair Hugger off. *Id.* Dr. Abraham found that the airflow patterns were the same regardless. *Id.* In fact, the experiments included clouds injected directly at the surgical site, which were halted and turned away by the clean airflow in the room. *Id.* In no case did airflow enter the surgical site from beneath the table, from the exhaust of the Bair Hugger, or any other location outside the sterile field. *Id.* He noted that these findings match those of the CFD calculations which were described earlier in his report. *Id.*

Plaintiffs claim that Dr. Abraham’s methodology is unreliable because he used a fog machine which “made it impossible for him to see the water vapor move around the room.” Pl. Mem. at 19. This claim is belied by videos which are publicly available and clearly show that the fog was visible, and that there is no difference in air flow near the

patient's head (behind the screen), underneath the table, or adjacent to the surgical site when the Bair Hugger was on or off.¹⁸ Plaintiffs simply speculate that the fog was no longer visible. Using a fog generator is an acceptable methodology. *See* Thomas J. Mueller, "Chapter 6: Flow Visualization by Direct Injection," in *Fluid Mechanics Measurements* 367 (Richard J. Goldstein, ed., 2d ed. 1996); Kennedy, "Water Fog as a Medium for Visualization of Airflows," 31 *Annals of Occupational Hygiene* 255 (1987).

Plaintiffs' critiques are also belied by the fact that Dr. Elghobashi failed to validate Dr. Apte's CFD model. Without validation, one cannot assume that computational models agree with the real-world validations.¹⁹

III. DR. ABRAHAM'S OPINIONS AND TESTIMONY MEET THE REQUIREMENTS OF FRYE-MACK.

In addition to meeting the Federal Rules' threshold for admissibility, Dr. Abraham's opinions and testimony should also be upheld under Minnesota Rule 702 and the *Frye-Mack* standard as expressed in *Goeb v. Tharaldson*, 615 N.W.2d 800, 814 (Minn. 2000). Dr. Abraham's CFD and airflow visualization study comply with CFD and validation methodology and were published.²⁰ In addition, the National Institutes of Health

¹⁸ Oddly, Plaintiffs critique Dr. Abraham for not attaching photos and videos of the airflow study to his report, but admit that the entire video is publicly available online. *See* <http://www.bairhuggerfacts.com/videos1/>. In addition, Dr. Abraham's publication of his CFD and airflow visualization study contains photos of the airflow visualization study.

¹⁹ According to NASA, CFD validation is "the process of determining the degree to which a model is an accurate representation of the real world from the perspective of the intended uses of the model." (<https://www.grc.nasa.gov/www/wind/valid/tutorial/valasses.html>).

²⁰ Minn. R. Evid. 702 states that a qualified expert's opinions and testimony are admissible if they have both: (1) foundational reliability, and (2) general acceptance in the relevant scientific community. *Goeb v. Tharaldson*, 615 N.W.2d 800, 814 (Minn. 2000). As

performed a CFD and also found that forced-air warming technology does not increase the risk of infections at the surgical wound site, confirming Dr. Abraham's conclusions.²¹ Dr. Abraham's testimony and opinions are therefore both "foundationally reliable" and "generally accepted" in the CFD and airflow visualization community. *Goeb*, 615 N.W.2d at 814. Further, Minnesota law agrees with this Court that "[t]he function of rebuttal testimony is to explain, repel, counteract or disprove evidence of the adverse party."

Signature Flight Support Corp. v. Cty. of Ramsey, No. 62-CV-14-3089, 2017 WL 1377751,

*1 (Minn. Tax Apr. 7, 2017) (quoting *Aviva Sports, Inc.*, 829 F. Supp. 2d at 834); *accord Whitney v. Buttrick*, 376 N.W.2d 274, 278 (Minn. App. 1985) (granting new trial based on district court's improper exclusion of rebuttal expert testimony). It is entirely appropriate for Dr. Abraham to critique Plaintiffs' experts' opinions, and he should be permitted to do so at trial in Ramsey County as well as in this Court.

CONCLUSION

In sum, Dr. Abraham offers opinions concerning the Bair Hugger system based on his own CFD and airflow visualization study, and a valid review of the scientific literature. He concludes that there is no compelling evidence that the use of forced-air warming systems such as the Bair Hugger meaningfully disrupt operating room airflow or increase

detailed above, Dr. Abraham's conclusion that there is no evidence that the Bair Hugger causes or increases the risk of surgical site infections is generally accepted in the scientific and medical communities.

²¹ Memarzadeh F., "Active warming systems to maintain perioperative normothermia in hip replacement surgery," 75(4) *J. Hosp. Infect.* 332 (2010). Dr. Elghobashi's CFD is contrary to the published conclusion of the National Institutes of Health.

the risk of surgical site infection by that purported mechanism. His opinions and conclusions are highly relevant and will assist the trier of fact in evaluating the merits of Plaintiffs' claims. His CFD and airflow visualization methodologies were reliable, and he provided all the necessary information to reproduce his results. Because Dr. Abraham has met the requirements of reliability and relevance, Fed. R. Evid. 702 and 703, Minn. R. Evid. 702, and controlling case law, Defendants respectfully request that the court deny Plaintiffs' Motion.

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Respectfully submitted,

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